THE STATE OF NEW HAMPSHIRE JUDICIAL BRANCH

SUPERIOR COURT

Strafford Superior Court 259 County Farm Road, Suite 301 **Dover NH 03820**

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SUMMONS IN A CIVIL ACTION



Case Name:

Colleen Perry v Insys Therapeutics, Inc.

Case Number:

219-2018-CV-00398

Date Complaint Filed: October 25, 2018

A Complaint has been filed against Insys Therapeutics, Inc. in this Court. A copy of the Complaint is

The Court ORDERS that ON OR BEFORE:

December 09, 2018

Colleen Perry shall have this Summons and the attached Complaint

served upon Insys Therapeutics, Inc. by in hand or by leaving a copy at his/her abode, or by such other service as is allowed by law.

December 30, 2018

Colleen Perry shall electronically file the return(s) of service with this Court. Failure to do so may result in this action being dismissed without

further notice.

30 days after Defendant

is served

Insys Therapeutics, Inc. must electronically file an Appearance and

Answer or other responsive pleading form with this Court. A copy of the Appearance and Answer or other responsive pleading must be sent

electronically to the party/parties listed below.

Notice to Insys Therapeutics, Inc.: If you do not comply with these requirements you will be considered in default and the Court may issue orders that affect you without your input.

Send copies to:

Michael Paul Rainboth, ESQ

Coughlin Rainboth Murphy & Lown 439 Middle Street

Portsmouth NH 03801

Insys Therapeutics, Inc.

1333 S Spectrum Blvd #100 Chandler AZ 85286

BY ORDER OF THE COURT

October 25, 2018

(931564)

Kimberly T. Myers

Clerk of Court

File Date: 10/25/2018 10:25 AM Strafford Superior Court E-Filed Decument

STATE OF NEW HAMPSHIRE
STRAFFORD, SS

SUPERIOR COURT
CIVIL ACTION DOCKET NO.
219-2018-CV-00398

Colleen Perry,

Plaintiff

vs.

COMPLAINT

Insys Therapeutics, Inc.

Defendant

Defendant

NOW COMES the Plaintiff, Colleen Perry, by and through her attorneys, Coughlin, Rainboth, Murphy & Lown, P.A., and complains against the Defendant, Insys Therapeutics, Inc., and alleges the following:

PARTIES

- 1. The Plaintiff, Colleen Perry, is an individual with a principal residence located at 11 Danielle Lane, Dover, New Hampshire 03820.
- 2. The Defendant, Insys Therapeutics, Inc. (hereinafter "Insys"), is a Delaware corporation with a principal place of business at 1333 S Spectrum Blvd #100, Chandler, AZ 85286. Insys is the manufacturer and provider of an opioid pain medication, Subsys.

GENERAL ALLEGATIONS

 In 2013 Colleen Perry was a patient at the PainCare clinic in Somersworth, New Hampshire, (hereinafter "PainCare") being treated for bilateral knee pain from a prior injury.

> COUGHLIN, RAINBOTH, MURPHY & LOWN, P. A. - ATTORNEYS AT LAW 439 MIDDLE STREET, PORTSMOUTH, NEW HAMPSHIRE 03801 This is a Service Document For Case: 218-2018-CV-00398 Strafford Superior Court 10/25/2018 1:59 PM

- At Paincare, the Plaintiff came under the care of Physician Assistant, Christopher 4. Clough.
- 5. Mr. Clough began treatment of the Plaintiff by providing prescriptions of numerous opioid medications including Actiq, a fentanyl medication, and performed injections to treat the Plaintiff's lower extremity pain. At that time, Ms. Perry did not have cancer.
 - On June 27, 2013 the Plaintiff went to PainCare for her normal monthly visit. 6.
- At that visit Mr. Clough told the Plaintiff that he had a new "miracle drug" for her 7. to replace Actiq. She objected and said she was doing well on Actiq and didn't want to switch. Clough persisted and persuaded the Plaintiff to go on Subsys telling her it was "much better than Actiq." He then wrote a prescription for a new fentanyl medication called Subsys. The initial dose was 400 mcg and was 4 times more than the FDA mandated initial dose of 100 mcg.
- Subsys (fentanyl spray) is a sublingual spray which is an opioid pain medication 8. classified as a schedule II substance which is much more potent than morphine and heroin.
- In January, 2012 the FDA had approved Subsys for the management of 9. breakthrough cancer pain in patients 18 years of age and older who are already receiving and are tolerant of opioid therapy for their underlying cancer pain. The mandated initial dosage was no more than 100 mcg.
- Subsys is subject to an FDA-required program known as "TIRF REMS" which 10. imposes rigorous controls on the prescribing and dispensing of medications which pose a risk of misuse, addiction and overdose.
- Upon information and belief, over 80% of the Subsys prescriptions to New 11. Hampshire patients during 2013 and 2014 were written by Christopher Clough, PA, while he was employed by PainCare in Somersworth, New Hampshire.

- 12. Within a few days of the visit in 2013, Ms. Perry received her first shipment of a box of Subsys which was delivered by Fed Ex from a company called Lindencare in New York.
- 13. At the same time, Mr. Clough was also prescribing other opioid medications for the Plaintiff to take along with the Subsys, including Actiq, another form of fentanyl.
- 14. On July 19, 2013 Clough increased the Subsys prescribed dose to 800 mcg. On September 25, 2013 Clough increased the dose to 1200 mcg every 4 hours.
- 15. Mr. Clough increased the prescribed dose of Subsys for Ms. Perry without medical justification until she was on the maximum dosage of 1600 mcg every 4 hours on February 9, 2014.
- 16. Ms. Perry became highly dependant on Subsys. On several occasions she lost consciousness due to the effects of Subsys and had to be revived by her husband who thought she had stopped breathing. She became nearly comatose on many occasions and was often in a "zombie" like state. She would fall asleep at work, at dinner and during conversations. Ms. Perry met with Clough and told him that she was not tolerating these high dosages of Subsys and that it was causing her to pass out. She asked him to reduce the prescribed dose. Clough continued to prescribe Subsys at the 1600 mcg level until November, 2014. He also began prescribing Opana 10 mg.
- 17. On November 24, 2014 Mr. Clough lowered her Subsys dose from 1600 mcg up to 5 times per day to 800 mcg and increased her Opana prescription to 30 mg.
- 18. Ms. Perry contacted Mr. Clough's office and told his assistant of her symptoms of severe withdrawal from Subsys.
- 19. Upon information and belief, Mr. Clough's license was under investigation in the latter part of 2014. His license was later suspended by the New Hampshire Board of Medicine in 2015 and was revoked in 2016. Mr. Clough told Ms. Perry that he was leaving the practice to do

work for his mother's charity business and going back to school instead of the real reason for his medical practice ending. This caused Ms. Perry to be ignorant of Mr. Clough's unethical, reckless and careless behavior which had caused the injuries inflicted upon her by Clough and Insys.

- 20. A new physician, Dr. David Tung at PainCare began supervising her care in December, 2014. He attempted to wean her off Subsys. He lowered her dosage from 800 mcg to 200 mcg to 100 mcg in a few months. Her last prescription for Subsys was on or about March 27, 2015. Ms. Perry again suffered extreme symptoms of withdrawal from Subsys being discontinued.
- 21. Recently, the New Hampshire Attorney General's office began an investigation of Mr. Clough's business dealings with Insys, the manufacturer of Subsys.
- 22. During this investigation, the Attorney General's office learned that patients in New Hampshire received more than 800 prescriptions and more than 100,000 units of Subsys in 2013 and 2014. During the Attorney General's investigation, it was determined that 84% of the Subsys prescriptions in New Hampshire were written by Physician Assistant Christopher Clough in 2013 and 2014 while he was employed at PainCare in Somersworth.
- 23. The New Hampshire Attorney General's office also discovered that Insys paid Mr. Clough approximately \$44,000.00 to promote Subsys at speaking engagements which the Attorney General's investigation revealed were a "sham". Apparently, these "events" were mostly social gatherings at high-end restaurants attended by Mr. Clough's family, friends and coworkers and not people who could prescribe Subsys.
- 24. Mr. Clough became a frequent speaker with the Insys Speaker Bureau. A former Insys District Sales Manager, who was recently arrested on federal anti-kickback charges described Clough in an email as a "crucial part of [Insys] Speakers Bureau.

- 25. The Attorney General's office discovered that Mr. Clough spoke at 39 programs between August 8, 2013 and October 16, 2014.
- 26. Between August 8, 2013 and November, 2014, Insys allegedly paid Mr. Clough \$44,000.00 for speaking at these events. Mr. Clough became one of the highest prescribers of Subsys in the country and the highest prescriber in New Hampshire. Upon information and belief, Mr. Clough prescribed Subsys to at least 157 patients.
- 27. On or about August 11, 2014 Mr. Clough received a Notice of Hearing from the New Hampshire Board of Medicine alleging inappropriate prescribing practices. A few days after that notice, Mr. Clough allegedly communicated with Insys and informed them that he was no longer willing to participate in their Speaker Bureau. The State of New Hampshire brought a lawsuit against Insys in the Merrimack County Superior Court, alleging that the Insys speaker programs conducted by Clough as a member of the Speaker Bureau were a scheme by Insys to provide payments to induce and in exchange for, prescribers to prescribe Subsys.
- 28. In March, 2017 Clough was arrested by Federal authorities on charges of receiving financial kickbacks in exchange for prescribing Subsys.
- 29. In September, 2018 Ms. Perry learned from one of her doctors that Clough's supervising physician at PainCare had been disciplined by the New Hampshire Board of Medicine for failing to properly supervise Clough. Prior to this she was unaware of Clough's arrest or indictment and was unaware of the involvement of Insys in allegedly paying kickbacks to Clough in the form of phony speaking engagement fees.
- 30. Shortly thereafter, the Plaintiff then researched Clough's name on the Internet and learned of his criminal arrest and the involvement of Insys in a fraudulent scheme to bribe prescribers of Subsys. The Plaintiff further learned of lawsuits against Insys for this fraudulent kickback/bribery scheme for the first time in September, 2018.

COUNT I

(FRAUD, CONSUMER PROTECTION AND NEGLIGENCE OF INSYS)

- 31. The Plaintiff repeats and realleges each and every allegation in Paragraphs 1-30 above as though fully set forth herein.
- 32. The Defendant, Insys had a duty abide by common law duties of care owed to patients who were receiving its drug and a duty to refrain from participating in the violation of the medical standard of care in the treatment of the plaintiff's chronic pain.
- 33. Upon information and belief, an Insys sales representative named Natalie Levine attended one of the Plaintiff's appointments and showed her how to use Subsys. Ms. Levine also attended some of the "Speaker Bureau" events at high-end restaurants in Portsmouth, NH. At these events, the Insys sales representative participated in forging the names of supposed attendees at several of these events who were not in fact in attendance at the restaurant.
- 34. Upon information and belief, an Insys sales representative also ordered and/or paid for more dinners at these restaurant events than were for people actually in attendance at the speaking event to make it look as if more people were at the event.
- 35. Upon information and belief, Insys fraudulently compensated Clough in a scheme to encourage him to prescribe extremely high doses of Subsys, in amounts which exceeded FDA guidelines contained within the TIRF-REMS mandatory program and which violated the standard of care for the treatment of the plaintiff's chronic pain.
- 36. Upon information and belief, Insys' sales representatives closely tracked the prescribing practices of providers such as Clough who were prescribing Subsys and were paid exorbitant bonuses by Insys which were directly tied to the amount of Subsys prescribed.

- 37. Thus, it is highly likely that representatives of Insys were aware of Clough's prescribing practices of Subsys, including the frequency and dosage amounts given to the plaintiff, and that they were inappropriate, dangerous and not medically justified.
- 38. Insys knew or should have known that the frequency and doses of Subsys being provided to the plaintiff by Clough and Linden Care were excessive, dangerous, inappropriate and in violation of the TIRF-REMS program and in violation of the medical standard of care for the treatment of chronic pain.
- 39. Upon information and belief, Insys pre-populated "OPT IN" forms and TIRF-REMS documents to mislead prescribers and insurance companies into prescribing and paying for Subsys.
- 40. Insys ignored the FDA requirement mandating the lowest possible dose, instead promoting, bribing and encouraging Clough to prescribe much higher and more dangerous doses to maximize profits which were contrary to the plaintiff's best interests.
- 41. Insys interfered with the doctor/patient relationship by encouraging its salespersons to remove confidential medical records from Clough's office for the purpose of deceiving the plaintiff's health insurance carrier to pay for Subsys.
- 42. The defendant, Insys, therefore breached the above-referenced duties and standards of care and acted fraudulently by bribing prescribers such as Clough and violated state consumer protection laws, and failed to abide by the TIRF-REMS program mandated by the FDA, proximately causing injuries to the plaintiff.
- 43. By engaging in the above described fraudulent and deceptive conduct, in the sale, marketing and promotion of Subsys, Insys engaged in unfair or deceptive acts or practices in violation of the New Hampshire Consumer Protection Act. Such acts violated Section 10 of the Consumer Protection Act entitling the plaintiff to double or triple damages and attorney fees.

- 44. When Ms. Perry was being prescribed dangerously high doses of Subsys, she had no idea that Insys was paying Clough kickbacks which totaled over \$40,000.00. Ms. Perry was also unaware that Insys was paying its sales representative, Natalie Levine, tens of thousands of dollars in bonus payments that were directly tied to the amount of Subsys being prescribed by Clough which rewarded both of them for high-dosage prescriptions. Ms. Perry was not aware of Insys' fraudulent actions until September, 2018.
- 45. As a direct and proximate result of the defendant's conduct as described above, the plaintiff was caused to suffer great pain of body and mind, past, present and future and has undergone medical care and treatment and expended money for such care and treatment which is likely to continue in the future. The plaintiff's ability to enjoy life has been adversely affected.
- 46. As the manufacturer and provider of Subsys, Insys had a duty to abide by and follow all federal and state regulations concerning the marketing, promotion, sale and distribution of Subsys.
- 47. The Defendant, Insys, failed to abide by federal and state law, in that the Defendant, Insys, promoted, marketed and arranged for the sale of Subsys to the Plaintiff's medical provider, Christopher Clough, PA, when such medication was only approved by the FDA for the management of breakthrough cancer pain and not for conditions such as lower extremity pain.
- 48. Insys fraudulently created a financial arrangement it had with Christopher Clough in that it paid him approximately \$44,000.00 to promote Subsys at "sham" Speaker events that were mere social gatherings at high-end restaurants attended by Clough's friends, family and members of the office staff of PainCare.

49. Upon information and belief, employees of Insys negligently misrepresented to the Plaintiff's medical insurer the medical condition of Ms. Perry in order to obtain insurance coverage for Subsys.

50. The Plaintiff is also entitled to enhanced compensatory damages from the Defendant for its wanton, willful, malicious and reckless conduct.

51. As a direct and proximate result of the Defendant's fraudulent conduct and violations of RSA 358-A, the Plaintiff was caused to suffer great pain of body and mind, past, present and future, has undergone medical care and treatment and expended money for such care and treatment. The Plaintiff's ability to enjoy his life has been adversely affected.

WHEREFORE, the Plaintiff respectfully requests that this Honorable Court award judgment against the Defendant in accordance with an amount to be determined at a Jury Trial, together with attorney's fees, costs and interest.

Dated at Portsmouth, New Hampshire this 25 day of October, 2018.

Respectfully Submitted Colleen Perry

By her Attorneys,

COUGHLIN, RAINBOTH, MURPHY & LOWN

Dated: October 25, 2018

Michael P. Rainboth, Esquire, Bar No.5586

439 Middle Street Portsmouth, NH 03801

(603) 431-1993

THE STATE OF NEW HAMPSHIRE

STRAFFORD, SS

SUPERIOR COURT

Colleen Perry

٧.

Insys Therapeutics, Inc.
Case No. 219-2018-CV-00398

ACCEPTANCE OF SERVICE

I, Michael D. Ramsdell, hereby accept service of Plaintiff Colleen Perry's Complaint in the above-captioned matter on behalf of Defendant Insys Therapeutics, Inc. ("Insys"), waiving any and all other formalities of service.

By accepting service, Insys does not waive any defenses, claims, or remedies it may have in this case, except as to adequacy of service.

Respectfully submitted,

INSYS THERAPEUTICS, INC.

By its counsel,

Dated: November 19, 2018

By: Michael D. Ramsdell (NH-Bar 2096)

RAMSDELL LAW FIRM, P.L.L.C.

46 South Main Street Concord, NH 03301 (603) 856-7489

mramsdell@ramsdelllawfirm.com